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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Ethical Considerations and Implications of Public Health Emergency Response with a Focus on the Current Ebola Virus Disease Epidemic

AGENCY: Department of Health and Human Services, Office of the Secretary, Presidential Commission for the Study of Bioethical Issues.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on ethical considerations and implications of public health emergency response with a focus on the current Ebola virus disease epidemic.

DATES: To ensure consideration, comments must be received by 5:00 p.m. EST on **[INSERT DATE 60 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments received after this date will be considered only as time permits.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by e-mail to info@bioethics.gov or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW, Suite C-100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202-233-3960. E-Mail: hillary.viers@bioethics.gov. Additional information may be obtained at <http://www.bioethics.gov>.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (the Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged with identifying and promoting policies and practices that ensure ethically responsible conduct of scientific research and health care delivery. Undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Commission is considering three areas of ethical concern raised by public health emergency response with a focus on the current Ebola virus disease (EVD) epidemic. The first area concerns U.S. public policies that restrict association or movement (such as quarantine), which have recently been proposed and/or employed for health care workers and military personnel returning from countries affected by EVD in western Africa. The second area concerns the ethics of placebo-controlled trials in the context of public health emergencies, and the EVD epidemic specifically, where the drug undergoing testing might be effective against the disease causing the

emergency. The third area of concern is the ethical considerations relevant to collecting and storing biospecimens during a public health emergency, such as the EVD epidemic, and sharing these specimens and associated data internationally for future research. At its meeting on November 6, 2014, the Commission heard from legal and medical experts in public health and infectious disease, and began its consideration of the complex ethical landscape of U.S. public health emergency response to the EVD epidemic.

The Commission is interested in receiving comments from individuals, groups, and professional communities regarding the three areas of ethical concern outlined above. The Commission is particularly interested in receiving public commentary regarding the following issues in the context of public health emergency response generally and the EVD epidemic specifically:

- Ethical and scientific standards for public health emergency response;
- Ethical and scientific standards that guide the use of quarantine or other movement restrictions during public health emergencies;
- The impact of quarantine or other movement restrictions on the availability or willingness of health workers to volunteer to contain the epidemic in disease-affected areas;
- The impact of quarantine or other movement restrictions on public fear and anxiety about potential threats to public health;
- How U.S. public policy and public health response to the current EVD epidemic might or should affect public attitudes to, and further U.S. policy and public health response to, other current and future public health issues and emergencies;

- Ethical and scientific standards for placebo-controlled trials during public health emergencies;
- Ethical and scientific standards for collection, storage, and international sharing of biospecimens and associated data during public health emergencies.

To this end, the Commission is inviting interested parties to provide input and advice through written comments.

Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: November 20, 2014.

Lisa M. Lee,
Executive Director,
Presidential Commission for the Study of Bioethical Issues.

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